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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/783,649

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Geoffrey N. Holland

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EXAMINER

RINES, ROBERT D

ART UNIT

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3686

MAIL DATE

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04/14/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/783,649	Applicant(s) HOLLAND ET AL.	
	Examiner R. David RINES	Art Unit 3686	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 December 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) none is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>20090112</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Notice to Applicant

[1] This communication is in response to the amendment filed 30 December 2008. It is noted that this application benefits from Provisional Patent Application Serial Nos. 60/509404 and 60/527583 filed 10/7/03 and 12/05/03, respectively. The Information Disclosure Statement filed 12 January 2009 has been entered and considered. Claims 1 and 12 have been amended. Claims 13-16 have been added. Claims 1-16 are pending.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

[2] Claims 1-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Engleson et al. (United States Patent #7,117,041) in view of Eggers et al. (United States Patent Application Publication #2006/0106649) and further in view of Bourget (United States Patent #6,647,299)..

As per (currently amended) claim 1, Engleson et al. disclose a medication management system, for use with an electronic network having one or more access nodes, the medication management system comprising: a medication management unit adapted for electronic communication with the electronic network, the medication management unit having a processing unit and a storage medium coupled to the processing unit (Engleson et al.; col. 14, lines 5-25 *see bedside CPU/medication management module); a medical device adapted for electronic communication with the electronic network and the medication management unit through use of one of the access nodes, the medical device having a processor and a memory coupled to the processor (Engleson et al.; col. 14, lines 5-46); wherein at least one of the medical device memory and the medication management unit storage medium contains programming code to determine the physical location of a medical device (Engleson et al.; col. 10, lines 45-61); and a user access device adapted for electronic communication with the medication management unit, the user access device displays the physical location of a medical device base on the report from the medication management unit (Engleson et al.; col. 10, lines 55-60).

Engleson et al. does not explicitly recite the use of the device access point to the network to determine location.

However, it is well-known in the art to utilize the access point of a device to the network to determine the location of the device. Accordingly, Eggers discloses a system wherein the location is based on which one of the access nodes was last used by the medical device and to report the last used access node to the medication management unit (Eggers et al; paragraphs [0056]-[0058] determines device location by connection to the network);

Neither Engleson et al. nor Eggers et al. disclose an audio alarm to pinpoint the device.

However, it is well known in the art to employ an audio signal or alarm to assist in locating a medical device, as evidenced by Bourget (Bourget; col. 3, lines 45-55). Specifically, Bourget employs an audio alarm to locate a medical device during telemetric transfer of data (Bourget; col. 3, lines 45-55).

NOTE: Regarding the recitation of “...alarm *to pin point the device*”, Examiner considers this to be a statement of intended use for the alarm.

Applicant has amended claim 1 with respect to the “audio alarm” to further specify; “...wherein the medical device has program code to activate and generate from the medical device an audio alarm signal....”

As per this element, neither Eggers et al. nor Engleson et al. disclose an audio alarm.

However, as evidenced by Bourget, the use of audible alarms for various purpose including device location is well known in the art (Borget; col. 3, lines 45-55). NOTE: Bourget emits the audible signal from the programmer in response to proximity to the patient sensor. Examiner considers the programmer to be a component and, therefor, a component of the device.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have combined the teachings of Engleson et al. with those of Eggers et al. and with those of Bourget. The combined teachings would have provided a system-enabled method of tracking and monitoring hospital clinical devices (Engleson et al.; col. 10, lines 45-61) Additionally, one of ordinary skill would have reasonably employed known network-based technologies to assist in determining the location of each device as a result of their respective connection points to the network (Egger et al.; paragraphs [0056]-[0059]). Lastly, such a combined system would have employed other well-known locating techniques such as audio to assist in locating the device (Borget; col. 3, lines 45-55). The motivation to combine the teachings would have been to optimize device distribution (Eggers et al.; paragraph [0058]) and to optimize the programming

link between an external programming unit and patient medical device (Bourget; col. 1, lines 7-12).

As per claim 2, Engleson et al. disclose a system wherein the user access device requests a report of the physical location of a medical device from the medication management unit (Engleson et al.; col. 10, lines 45-60).

As per claim 3, Eggers discloses a system wherein the medication management unit contains the programming code and provides the report of the last used access node when the medication management unit receives a request for a report of the physical location from the user access device (Eggers et al; paragraphs [0056]-[0058] determines device location by connection to the network).

As per claim 4, Eggers et al. disclose a system wherein the medical device contains the programming code and reports the last used access node to the medication management unit when the medical device receives a request for a report of the last used access node from the medication management unit (Eggers et al; paragraphs [0056]-[0058] determines device location by connection to the network).

1083 - (10/783,649) 5, Eggers et al. disclose a system wherein the medical device contains the

programming code and periodically determines the last used access node (Eggers et al; paragraphs [0056]-[0058] determines device location by connection to the network).

As per claim 6, Eggers et al. disclose a system wherein the medical device contains the programming code and periodically reports the last used access node to the medication management unit (Eggers et al; paragraphs [0056]-[0058]).

As per claim 7, Eggers et al. disclose a system wherein the medication management unit contains the programming code and periodically determines the physical location of the medical device based on the last access node used by the medical device (Eggers et al; paragraphs [0056]-[0058] determines device location by connection to the network).

As per claim 8, Engleson et al. disclose a system wherein the medication management unit contains the programming code and periodically reports the physical location of the medical device to the user access device (Engleson et al.; col. 9, lines 58-67, col. 10, lines 45-61, col. 11, lines 1-14).

As per claim 9, Engleson et al. disclose a system wherein the user access device is remotely located from the medication management unit (Engleson et al.; col. 9, lines 58-67, col. 10, lines

45-61, col. 11, lines 1-14 *see access via network CPU's).

As per claim 10, Engleson et al. disclose a system wherein the user access device comprises a computer located in a biomedical technician area (Engleson et al.; col. 10, lines 55-61 *see "bursing CPU").

As per claim 11, Eggers et al. disclose a system wherein the user access device comprises a PDA (Eggers et al.; paragraphs [0025] [0056]).

As per (currently amended) claim 12, Eggers et al. disclose a method for tracking a medical device connectable with an electronic network having one or more access nodes, comprising: determining the last access node used by a medical device and reporting the last used access node to a medication management unit (Eggers et al; paragraphs [0056]-[0058]); determining the physical location of a medical device based on the last access node used by the medical device as reported at the medication management unit (Eggers et al; paragraphs [0056]-[0058]).

Eggers et al. fail to explicitly recite the production of a report or displaying the device locations.

However, Engleson et al. disclose displaying the physical location of a medical device at a user access device, based on a report from the medication management unit (Engleson et al. col. 10, lines 45-67, col. 11, lines 1-14).

Neither Engleson et al. nor Eggers et al. disclose an audio alarm to pinpoint the device.

However, it is well known in the art to employ an audio signal or alarm to assist in locating a medical device, as evidenced by Bourget (Bourget; col. 3, lines 45-55). Specifically, Bourget employs an audio alarm to locate a medical device during telemetric transfer of data (Bourget; col. 3, lines 45-55).

Applicant has amended claim 12 with respect to the “audio alarm” to further specify; “...wherein the medical device has program code to activate and generate from the medical device an audio alarm signal...”

As per this element, neither Eggers et al. nor Engleson et al. disclose an audio alarm.

However, as evidenced by Bourget, the use of audible alarms for various purpose including device location is well known in the art (Bourget; col. 3, lines 45-55). NOTE: Bourget emits the audible signal from the programmer in response to proximity to the patient sensor. Examiner considers the programmer to be a component and, therefor, a component of the device.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have combined the teachings of Engleson et al. with those of Eggers et al. and with those of

Bourget. The combined teachings would have provided a system-enabled method of tracking and monitoring hospital clinical devices (Engleson et al.; col. 10, lines 45-61) Additionally, one of ordinary skill would have reasonably employed known network-based technologies to assist in determining the location of each device as a result of their respective connection points to the network (Egger et al.; paragraphs [0056]-[0059]). Lastly, such a combined system would have employed other well-known locating techniques such as audio to assist in locating the device (Bourget; col. 3, lines 45-55). The motivation to combine the teachings would have been to optimize device distribution (Eggers et al.; paragraph [0058]) and to optimize the programming link between an external programming unit and patient medical device (Bourget; col. 1, lines 7-12).

As per (newly added) claim 13, Engleson et al. disclose a method wherein the medical device is selected from a group of medical devices consisting of a medical pump, a medical diagnostic device, and a patient vital signs monitor (Engleson et al.; col. 6, lines 38-50 col. 10, lines 45-60 *see infusion pump or vital sign sensor).

As per (newly added) claim 14, while Engleson et al. disclose alarms and alerts, Engleson et al. fail to teach a delayed alert. Eggers et al. disclose time delay functions for various device functions (Eggers et al.; paragraph [0048]).

Eggers et al. fail to specifically disclose time delay associated with an alarm, however, it would however, it would have been obvious to one of ordinary skill in the art to have applied the time delay features of Eggers et al. to any of the noted functions with the motivation of locating the device and optimizing utilization of hospital equipment (Eggers et al.; paragraph [0058]).

A per (newly added) claim 15, Engleson et al. disclose a system wherein the medical device is selected from a group of medical devices consisting of a medical pump, a medical diagnostic device, and a patient vital signs monitor (Engleson et al.; col. 6, lines 38-50 col. 10, lines 45-60 *see infusion pump or vital sign sensor).

As per (newly added) claim 16, while Engleson et al. disclose alarms and alerts, Engleson et al. fail to teach a delayed alert. Eggers et al. disclose time delay functions for various device functions (Eggers et al.; paragraph [0048]).

Eggers et al. fail to specifically disclose time delay associated with an alarm, however, it would however, it would have been obvious to one of ordinary skill in the art to have applied the time delay features of Eggers et al. to any of the noted functions with the motivation of locating the device and optimizing utilization of hospital equipment (Eggers et al.; paragraph [0058]).

Regarding claims 13-16, the statements of obviousness and motivation to combine as discussed with regard to claims 1 and 12 above are applicable to claims 13-16 and are herein incorporated by reference.

Response to Remarks

Applicant's remarks filed 30 December 2008 have been fully considered but they are not persuasive. The remarks will be addressed below in the order in which they appear in the noted response.

Applicant remarks that the combination of Eggers et al., Engleson et al., and Bourget, does not describe the system defined by claim 1 of present application.

Applicant substantially remarks that Bourget fails to disclose an audio alarm from the device. Specifically, Applicant notes that the audio alarm employed by Bourget emits the alarm sound from the programmer in response to locating an implanted device and does not emit an alarm sound directly from the implanted device.

In response, Examiner agrees that the audible alarm disclosed by Bourget, which is used to locate the implant component of the medical device, is emitted by the programmer component of the device as opposed to the implanted component. Presumably, this configuration is used by Bourget, as noted by Applicant, because it would be impractical to emit an audible noise from the sensor implanted in the patient.

Initially, Examiner notes that Bourget is applied in the rejection of the noted claims merely to evidence that audible alarms emitted from medical devices are well known in the art for a variety of uses including, as taught by Bourget, to locate a medical device. NOTE: Examiner considers the statement "to pinpoint the device location" as a statement of intended use for the alarm.

Further, Examiner directs Applicant's attention to the claim language as presented. Claim 1 as presently constructed requires ... "program code to activate and generate from the medical device an audio location alarm signal...". The alarm configuration disclosed by Bourget employs a bi-directional communication link between a programmer and an implanted device to trigger the audio alarms (Bourget; Abstract and col. 3, lines 45-55). Examiner submits that the alarm is generated based on the bi-directional communication between the two components and is thus "generated" from the "signal" between the two components. It is audibly projected from the external component. As noted above, Examiner considers the external component to be a part of the medical device. Examiner respectfully submits that the relationship between the two components (i.e., a signal) and the associated alarm emitted to locate the implanted component constitutes "activate[ing] and generat[ing] from the medical device an audio location alarm signal..." at least insofar as presently claimed by Applicant.

In conclusion, all of the limitations which Applicant disputes as missing in the applied references, including the features newly added in the 30 December 2008 amendment, have been fully addressed by the Examiner as either being fully disclosed or obvious in view of the

collective teachings of Engleson et al., Eggers et al., and Bourget, based on the logic and sound scientific reasoning of one ordinarily skilled in the art at the time of the invention, as detailed in the remarks and explanations given in the preceding sections of the present Office Action and in the prior Office Action (30 June 2008), and incorporated herein.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to R. David RINES whose telephone number is (571) 272-5585.

The examiner can normally be reached on 8:30am - 5:00pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, JERRY O'CONNOR can be reached on (571) 272-6787. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or (571) 272-1000.

/R. D. R./
Examiner, Art Unit 3686
April 13, 2009

/Gerald J. O'Connor/
Supervisory Patent Examiner
Group Art Unit 3686